

Remarks

To expedite prosecution, Applicants have amended claims 12, 13 and 14 to specifically refer to the exemplary algae species used in the Examples, namely *Chaetoceros gracilis* and *Skeletonema costatum*. Claims 1 and 2 previously directed to these two algae species have thus been cancelled without prejudice. Accordingly, no new matter has been introduced by the amendments and their entry is respectfully requested.

Rejections under 35 USC § 112

The Examiner rejected claims 1-6, and 11-12 as allegedly not complying with 35 U.S.C. §112, first paragraph written description requirement. The Examiner alleged that that the specification fails show that the Applicant was in possession of the invention at the time of filing. Specifically, the Examiner alleged that the Applicants have not shown possession of a method using any and all species under *Chaetocerotaceae* or *Skeletonemaceae*, because only one exemplary species has been used in the specification for each of these families.

Applicants respectfully disagree and submit that the rejection should be withdrawn for the following reasons.

The two exemplary species used in the experiments set forth in the specification are *Chaetoceros gracilis* and *Skeletonema costatum*. Claims 1 and 2 were drawn to these species specifically. Therefore, the rejection should not be applied to claims 1 or 2.

Also, while Applicants respectfully disagree with respect to the rejection as it is applied to claims 3-6 and 11-12, because the metabolic pathways of the various species of *Chaetocerotaceae* or *Skeletonemaceae* are known to be very similar and a skilled artisan would have been able to extrapolate the results from the experimental models used in the specification, to expedite prosecution, Applicants have amended the claims to only apply to the two specifically exemplified species set forth in claims 1 and 2. To comply with the amendment, claims 1 and 2 have been canceled.

Accordingly, in view of the above, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph written description requirement, should be withdrawn.

Rejections under 35 USC § 103

The Examiner rejected claims 1-6 and 12-14 under 35 USC 103(a) over previously cited McGinnis, taken with a newly cited Reitan et al. (Journal of Phycology 30(6): 972-979, 1994)(“Reitan”), and previously cited Dempster and Taguchi. Specifically, the Examiner alleged that Reitan describes a “semi continuous” culture for the production of PUFAs, and thus, any optimization to the claimed method which also uses a semi-continuous system in view of Reitan and the teachings of McGinnis, Dempster and Taguchi is obvious.

Applicants respectfully disagree and submit that the rejection should be withdrawn for the following reasons.

The Examiner interpreted all references describing methods wherein “at least some cells are in exponential growth phase”. As already discussed in the prior response, this interpretation is incorrect because the claims refer to “culture” as a whole, not individual cells. The term “exponential growth phase” of an algae culture has a well-known meaning in the art as referring to the growth profile of a culture - not to the growth of any particular cell within that culture (see also Exhibit A, attached herewith). Moreover, the claims specifically recite “**culture**” as opposed to “at least some diatoms were in exponential phase.”

The Examiner further appears to equal the terms “**at the end** of exponential phase” to “**after the end** of exponential phase”, thereby incorrectly construing the claims. There is a significant difference in the phrases, “at the end” of exponential phase refers to a culture that has not yet entered a stationary growth phase, whereas, “after the end” of exponential phase, the term the Examiner himself is using, refers to the stationary growth phase, which is not what is claimed. In view of the well known growth phases of algae, the Examiner’s contention regarding the teaching of the prior art is incorrect. All the cited references specifically teach cell manipulation at the stationary phase, not at the end of exponential growth phase.

For example, as already discussed earlier, McGinnis specifically taught a deprivation of nitrogen at day 4. Page 20, second column of McGinnis, shows that the **cells were at the stationary phase**, not at the end of exponential phase which is what is claimed. McGinnis Figure 3, by day-two the culture had reached the peak of exponential growth, and by day-four (as indicated by the horizontal line evidencing that cell growth rate equaled cell death rate in the Figure attached to the

previous amendment), the culture had passed into stationary phase. Indeed, McGinnis specifically states that “By Day 3, **growth reached stationary phase.**” (page 21, col. 1). Accordingly, as stated before, nothing in McInnis teaches, suggests or lets a skilled artisan to expect success for a method that uses cell in exponential rather than stationary phase.

Taguishi does not cure the deficiency in McInnis, namely, also Taguishi does not teach that the culture is at the end of exponential phase. Rather, Taguishi teaches, at Fig. 1, deprivation test was conducted **at the stationary phase and not at the exponential phase** (see positioning of arrows in Fig. 1 of Taguishi). In addition, the effect is measured using total lipid content and nothing is mentioned regarding enrichment of PUFA.

The newly cited Reitan also does not cure the deficiency in McInnis because it does not teach adding a growth limiting factor at the end of the exponential growth phase. Reitan only teaches comparative study of nutrient limitation on fatty acids and lipid content in various species. The conclusion is that PUFA are diminished, which is also contrary to the findings in the present invention.

Dempster fails to cure the deficiency in McInnis because also the cultures in Dempster are in stationary growth phase, as is clear from the nitrogen stress which is conventionally applied at the stationary phase.

By contrast, as taught be the instant application and recited in the claims: “After 6-7 days ... the algae **cultures** were at the end of their exponential growth phase. **Only at the end of the exponential growth phase were the algae stressed...**” ([0016] emphasis added)

Accordingly, the combination of the cited references does not teach all the elements of the claims, namely, the element of applying at least one growth limiting factor **at the end of** exponential growth phase, is not taught or suggested in any of the cited references. There is also no indication that silicate deprivation initiated at the end of exponential growth phase is critical for the result of in an increase in Omega-3 fatty acid production in the claimed cultures of *Chaetoceros gracilis* and *Skeletonema costatum* algae species now claimed. Therefore, the cited references do not combine to provide for the claimed invention.

In view of the above, Applicants respectfully submit that the rejection under 35 U.S.C. 103(a) should be withdrawn.

Conclusion

In view of the foregoing, Applicants respectfully submit that all the pending claims are in condition for allowance. At minimum, the amendments to the claims and the additional evidence presented into the file will reduce issues on appeal. Early and favorable action is requested.

The Commissioner is hereby authorized to charge any fees, such as additional claims fees, and credit any overpayments that may be due in connection with this submission to Nixon Peabody LLP Deposit Account No. 50-0850.

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Respectfully submitted,

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